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Epidemiologic Burden of Medication Errors that do not Reach Patients

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Abstract

The term “near miss,” often employed in discussions about medication errors that do not reach patients, embraces ambiguity. It refers variously to an error that was detected and recovered prior to administration; to an error that could have affected a patient, irrespective of whether it was intercepted; to a process overwhelmingly devoid of direct individual consequence; or—a rare distinction—to checks of a patient’s record owing to uncertainty perceived by the deliverer. Such variability obstructs consensus upon metrics appropriate for summarizing the phenomenon the term is meant to signify. Towards protecting the intended referent from co-optation by inapposite observations, the present effort persists in framing the consideration as near-miss errors, thereby accompanying the term “near miss” with a qualifying modifier. Progress ultimately fashions a precise shared definition suited for formal definition in future usage.

Frameworks for modeling and describing the myriad complexities surrounding the phenomenon of near-miss errors present significant appeal. By organizing error-generating work processes temporally and conceptually, such frameworks rigorously delineate distinctions among stages of operation and clarify distinctions among contributing factors. Elements of these frameworks offer direct support to a generic definition appropriate for research settings. The framework selected for further articulation, originally proposed for the independent analysis of error-generating processes affecting diagnostics and treatment, retains usefulness within the present consideration. Processes contributing to near misses abide by the generic classification containing the four categories of prescribing, transcribing, dispensing, and administering.

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1. Introduction

Medication errors constitute a substantial burden on public health, affecting patient safety and quality of care across healthcare systems (Mulac et al., 2021). Errors can arise at various points during the medication-use process—including physician orders, healthcare provider transcriptions, pharmacy dispensing, and drug administration—potentially jeopardizing patient health and safety (Parthasarathi et al., 2021). The World Health Organization recognizes medication errors as a top priority for patient safety, estimating that their elimination could prevent approximately 50% of adverse drug events (Garzón González et al., 2019).

Notably, not all medication errors reach patients. Errors that do not reach patients—ultra-rare, near-miss medication errors—represent an equally significant but largely unexplored area of the medication-error literature. Established literature on the subject emphasizes that the health system can still capture important lessons from near-miss events, which, classified as medical errors detected and intercepted before patient contact, provide insight into the functioning of medication systems and their resilience. By permitting structured safety-event analyses without encroaching on patient confidentiality or diverting focus away from high-incidence mistakes, near-miss data foster enhanced conceptions of safety and support the development of systemic and organizational correctional measures.

The present study characterizes the epidemiology of ultra-rare, near-miss medication errors in order to delineate the degree of attention they warrant among safety stakeholders. A specific, tailored set of questions addresses the relevant concepts, definitions, data sources, and measurement-facilitating framework. The perspective on safety adopted by the study policies further enhances its potential relevance and originality.

Information is presented in a manner conducive to knowledge acquisition, with the study reference materials underpinning conceptual performance. Integrating detailed analytical systemic contributions enables the near-miss error conceptualization to sit at the core of and guide the entire progression, thereby ensuring clarity and systematic progression throughout the analytical journey.

2. Conceptual Framework and Definitions

Near-miss medication errors are potential medication errors that do not reach the patient. A formal definition is an event that involves a drug, dose, patient, or route that differs from the

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actual order, yet no part of the order reaches the patient. The following describes the conceptual framework and constructs associated with near-miss errors. A conceptual model illustrates four pathways through which near misses occur, using five generic mechanisms that operate within each pathway (Parthasarathi et al., 2021). These encompass prescribing, transcribing, dispensing and administration errors. Near-miss phenomena are extremely common in medication use in hospitals. The various types of near-miss errors are prescribed drugs that have not been transcribed, transcribed order never sent to pharmacy, a prescription that has been sent to the pharmacy but not dispensed, and dispensed drugs to the patient not given at the point of administration. Other classes of near miss are failures of technology, system revision, human factor interrelation and workflow interruptions (Rattanarojsakul & Thawesaengskulthai, 2013). A number of metrics can be employed to quantify the burden of near-miss errors. Although many different definitions of medication error have been used in the literature, two specific metrics often used are incidence and prevalence.

Incidence considers the frequency of occurrence of a phenomenon during a given time period, treating that point in time as a starting point. This is normally expressed as cases per 1000 patient-days or similar unit over, for example, a month, year, or decade. In contrast, prevalence considers how widespread the phenomenon has become. Prevalence is reported as the total number of cases among a population at a given time and is often expressed as cases per given count, e.g. 100 hospital bed, active patients, or number of drugs prescribed. A solution in the absence of complete annotation of incident data is to use a hypothetical near-miss error incidence rate. The presence of near-miss error occurrence suggests that medication errors is an active concern within the system, albeit stopped at the first checkpoint. A more precise timeframe is avoided due to the limitation of number of the total artefacts volume allowing for analysis while maintaining confidentiality in patient-identifying and institution info remain essential.

3. Magnitude and Burden: Metrics and Measurement

Medication errors (MEs) are largely preventable events that can cause patient harm. They include prescribing, preparation, dispensing, administration, and monitoring tasks related to medication therapy. The World Health Organization (WHO) estimates that 1 in 10 medication errors results in harm to patients, and the economic burden of preventable harm from medications exceeds US$42 billion annually (Parthasarathi et al., 2021). A high incidence of MEs—44 per 100 hospital admissions—was also observed at a university hospital in Turkey. These alarming statistics highlight the need to promote patient safety in medication management and improve the quality of healthcare (M. Jambrina et al., 2022).

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4. Pathways and Mechanisms of Near-Miss Errors

Near-miss error phenomena manifest throughout the pharmacotherapy process. Conventional approaches consider four stages of medication use (prescribing, transcribing, dispensing, administration) where errors could occur. However, it is useful to extend these stages beyond these conventional boundaries to accommodate subsequent error-generating processes that are initiated during transcribing and dispensing. These extend until the final act of administration, whereby the medication is given to the intended patient and is administratively documented in a patient record. Simple conceptual models emphasize two classes of error paths: failure to provide administered medications and provision to patients of erroneously selected or improperly specified medications. Additional pathways also capture transfers of responsibility from prescriber to pharmacist, and from pharmacist to nurse, that are integral to the medication process. Concepts, terminology, measures, and associated metrics clarify that near-miss errors are repetitive events wherein the same error is prevented on a subsequent occasion after having previously occurred under an earlier system configuration (M. Jambrina et al., 2022).

The International Society for Quality in Health Care has defined near-miss events as “an event or situation that did not produce patient harm, although reaching the patient.” Near-miss events occur without patient effect and are therefore strictly distinguished from actual errors. The widely adopted five r’s criteria identify five fundamental attributes required to safely administer any medication to a specific patient: the “right” patient, drug, dosage, time, and route. These represent the operational point of reference for characterizing an error type and assessing an error condition. The recording of administered medications and associated attributes in hospital information systems therefore fundamentally guides the delineation of near-miss events.

5. Surveillance and Data Sources

Passive surveillance systems are designed for spontaneous reporting and are a key data source for cumulative knowledge building and various patient safety isb2bbc9c8-b407-47c8-b5c5-634834086452s, including medication errors (Laatikainen et al., 2020). Examples include the US MedWatch and FDA Adverse Event Reporting System, the UK’s National Reporting and Learning Service, Germany’s System for the Reporting and Analysis of Adverse Events, and Canada’s Canadian Medication Incident Reporting and Prevention System (CMIRPS). Initiated in 2015, the Global Trigger Tool is a notable international approach that follows a similar principle and seeks to identify various adverse events, including medication-related occurrences. Although primarily aimed at actual adverse events,

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reported near misses are also noted. In Canada, CMIRPS reports have highlighted near-miss medication errors as a key concern (Sue Mah-Fraser, 2010).

Other types of surveillance systems collecting additional information include active monitoring, electronic medication incident data extraction, ad hoc trigger tool studies to identify a range of patient safety events, and the use of statistical accident models to forecast error behaviour. Descriptive data about near misses may also be gathered through chart reviews, queries of pharmacist incident reports, linkages between multiple data sources (e.g., pharmacy-relevant and patient-relevant electronic health records), analysis of spare-parts through a select number of sentinel sites for upfront or generic classification, and structured frameworks and indicators for periodic quality audits.

6. Risk Factors at System, Clinician, and Patient Levels

Explanatory factors at the system, clinician, and patient levels shape near-miss medication errors and their potential to harm patients. The organizational culture of a healthcare system, practice environment, work processes, and the usability of computerized systems influence the frequency of near misses. For example, high turnover of personnel and unfilled staffing positions can compromise supervision and services; poorly designed or complicated technologies that impede rather than facilitate work magnify the risk of error; and unclear communication among professionals and between professionals and patients can lead to misunderstanding and the potential for error (Sue Mah-Fraser, 2010).

Characteristics of individual clinicians—including task fatigue, excessive workload, lack of training in safe medication practices, and several distractions—affect error generation and capture. Patient characteristics such as age, cognitive competence, health literacy, and literacy level also contribute, as do active involvement and participation in the medication-use process (Barbosa de Aguiar et al., 2018).

7. Consequences and Implications for Safety Culture

Medication errors that do not reach patients may seem inconsequential, yet they highlight systemic vulnerabilities and undermine an organization’s safety culture (Al Mutair et al., 2021). These errors pose no direct risk of harm but can indicate potential safety lapses and proliferate under similar conditions. Such events merit systematic analysis and preventive action that reinforces, rather than contravenes, existing safety initiatives. The construal of safety culture involves establishing a blaming and punitive environment, because these errors present an opportunity for learning without attaching individual culpability.

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Near-miss medication errors occur throughout the medication-use process. These errors typically arise from inadequate environmental preparation and suboptimal functioning of medical devices. Vital prescriptions by physicians in primary care and multiple reused orders in repeat prescriptions are additional contributing factors. Deciphering virtually illegible health professionals' prescriptions and inputting correct and timely information are among the causes of transcribing errors. Late medication administration, delayed resolution of urgent medication requisitions, administration at unplanned units, and diversion of medication to unplanned patient movements give rise to dispensing errors.

8. Interventions: Pre-emptive and Reactive Strategies

Approaches to prevent or mitigate medication errors are generally classified as either pre-emptive or reactive. Pre-emptive strategies act before a medication error occurs, while reactive strategies come into play after the error has already happened.

Various exemplary pre-emptive strategies include computerized physician order entry systems, computerized surveillance programs to monitor antibiotic usage, drug formulary controls, and patient alert systems. Computerized physician order entry systems have been shown to reduce prescription errors, particularly when combined with clinical decision-support tools (G Anderson et al., 2002). Drug formulary controls promote the use of low-risk medications through mandatory justification of high-risk orders, and computerized alerting systems help manage drug allergies and other high-risk orders. Computerized surveillance systems for monitoring antibiotic use have led to significant reductions in the unnecessary use of such drugs.

Some reactive strategies include incident-reporting systems, education, and feedback. Incident-reporting systems, although common, often fail to detect many errors, particularly those that do not reach the patient. Substantial educational and training support, as well as constructive feedback, are also needed to ensure the continued effectiveness of preventive strategies.

9. Evaluation of Interventions: Methods and Challenges

Near-miss errors may result from similar systemic weaknesses without causing harm. Although not formally defined, the concept is well established in accident investigation (Savage et al., 2010). Because near-misses do not always progress to an actual error, they are often difficult to detect. Interventions can therefore tighten controls over potentially hazardous situations before they escalate. Systematic collection of these events constitutes an essential pre-condition for mitigation of the associated risks. Various intentional and

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unintentional mechanisms provide safety against near-miss errors. Technological measures, such as computerized decision support and improved access to records, supplement more human-centered strategies involving normalisation of deviance, training, and feedback loops. Evaluations may clarify whether approaches sidestep new or sharper hazards. Pre-emptive safety strategies enable confinement within a socio-technical framework of complex interactions among users, technologies, tasks, and broader organizational context. Reactive methods indicative of embedded, self-amplifying systems emphasize incident management and learning, thus ensuring safety through resilience (G Anderson et al., 2002). In extreme cases, exposure to systematic error biases safety perceptions towards reliance solely on intervention.

Study design informs the ability to detect changes in aspects of pre-emptive or reactive activity that shape primary selection among types of near-miss, actual-error, or other events. Measures should encompass targeted near-misses and normal near-misses. Although guidance persists regarding design box criteria and constraints, limited empirical input hampers further elaboration. Criteria identification and analysis of possible biases signal realization of requisite additional insight and information. Many evaluations report on general economic impact, adopting widely accepted procedure scales. Though metrics prove simpler for economic assessment of non-patient-harmed events, evident obstacles inhibit their determination in absence of standard practice. Pre-existing data gathered from other studies potentially serve investigations across diverse health services, countries, and settings (Boostani et al., 2019).

10. Policy and Regulatory Considerations

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Policy and Regulatory Considerations

Various reporting requirements exist at the national and regional levels, targeting specific classes of incidents or overall safety culture and associated risk factors. In Australia, the National Safety and Quality Health Service (NSQHS) Standards, an accreditation framework linked to the Australian Commission on Safety and Quality in Health Care (ACSQHC), define medication safety goals. Each goal is supported by a set of guidelines that identify areas for improvement. In the United Kingdom, the Department of Health and Social Care and the National Health Service (NHS) England and Improvement have established a series of safety targets that includes reducing the incidence of medication errors. These documents recognize that near-miss errors fall outside the scope of mandatory notification but emphasize the need to address and monitor them because of their implications for patient safety.

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The European Medicines Agency (EMA) and the European Commission have jointly seen the need for enhanced cooperation and optimization of existing reporting systems dedicated to medication errors and the comprehensive analysis of trends. The harmonization of definitions and reporting practices is also mandated. A Regulation on medical devices sets the obligation to establish a system of vigilance covering incidents, near misses, and other risk factors; to make such a system interoperable with the one established for medicinal products; and to transmit aggregated aggregate and codified data at the same time. The Investigation of Medicinal Product-Related Risks and Risk Minimization Measures provides the framework for the preparation of risk evaluation and mitigation strategies.

Interoperability among electronic health records is increasingly considered essential to share near-miss safety information. The United States 21st Century Cures Act calls for a term "interoperability" that addresses the homogeneity among the electronic records to permit the safe and adequate exchange of health information that would impact medication safety. The applicability of the proposed interoperability standards to near misses has been recognized, as such incidents constitute "multiple successive failures" that point to an elevated risk of eventual serious incidents, warranting attention at the system level. The transparency of near-miss events has been stated; sharing and addressing them at a systems level instead of an individual level might thus reinforce a properly functioning safety culture (E. Hoeve et al., 2020).

11. Gaps in Knowledge and Future Research Directions

Despite important progress toward reducing medication errors, they continue to cause substantial patient harm (Mulac et al., 2021). Near-miss medication errors are defined as events that are not intercepted before reaching a patient. Such errors represent a major yet often overlooked aspect of medication safety, and understanding their epidemiologic burden holds important implications for the safety culture of health care systems (Sue Mah-Fraser, 2010). An epidemiologic framework is proposed to guide investigation into the occurrence and characteristics of near-miss errors. The approach highlights key questions regarding the type and magnitude of near misses, the pathways through which they occur, the factors influencing error generation, and the consequences for safety culture. Several epidemiologic concepts are introduced to facilitate precise communication about the study of near-miss medication errors. A definition of near miss is articulated, a conceptual model detailing the pathways through which errors are generated is presented, and metrics for estimating the occurrence of near misses are outlined. Finally, promising data sources and existing surveillance systems are identified to support future research.

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12. Conclusion

Given that human factors drive medication errors across diverse healthcare settings, countries and jurisdictions, the burden should ideally be characterised solely in terms of the error-generating processes through which it accumulates—irrespective of whether any particular error actually reaches a patient and/or has the potential to inflict harm (Parthasarathi et al., 2021). However, both traditional and contemporary patient safety literature—and the resulting lessons for safety culture—differ dramatically in their perceptions and acknowledgement of near-miss errors (Mulac et al., 2021). For the first time in the literature, an epidemiologic526 overview of near-miss medication errors—whose definition, framework and metrics were painstakingly laid out above—is articulated. When viewed through the lens of that epidemiology, a clear understanding emerges of the predominant pathways via which the near-miss phenomenon manifests; the typical system, clinician and patient-related factors associated with it; the serious consequences that follow even in the absence of medication; and the sweeping, pre-emptive, reactive and evaluative interventions capable of effectively mitigating further occurrences.

To advance the safety agenda, a small number of high-impact, transdisciplinary studies ought to be prioritised at this juncture. Tracking the factors associated—positive and negative—with the completion of near-miss errors throughout the decision-implementation cycle, to strengthen further the still-vastly under-utilised concept in medication safety. Exploring variations in the determinants and content of near-miss reports originating from different hospitals and regions, to facilitate targeted improvement of system redesigns and safety communications. And documenting the societal costs linked to the emergence of near-misses and their resourcing requirements, to make the case for dedicated, system-wide investments in safety culture. Despite the all-too-frequent evidence to the contrary, the systems that comprise healthcare—from the individual organisation through to the overarching institutions and economies—remain resilient and capable of learning from their errors. Medication errors that reach patients and have the potential to cause harm undoubtedly inflict serious, regrettable consequences; the far larger burden of near-miss errors constitutes a more insidious, covert, yet still resource-intensive phenomenon that only reinforces the need for a comprehensive understanding and concerted action to curtail it.

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